

**REMARKS**

Reconsideration of this application is requested. The issues raised in the Action are now addressed.

**Claim of benefit of U.S. Provisional Application No. 60/097,071.** Applicants claim benefit of this prior divisional application filed August 19, 1998. A signed and dated supplemental Declaration and Power of Attorney for this patent application is submitted concurrently with this response. The current application 09/376,487 was filed on August 18, 1999 as a non-provisional application within the one-year time period after priority U.S. Provisional Application 60/097,071 was filed on August 19, 1998.

(II) **Rejections under 35 U.S.C. § 103(a).** Because the current application claims the benefit of U.S. Provisional Application 60/097,071 filed on August 19, 1998, and because the documents cited by the examiner, i.e., Pejaver et al. (US 6,100,302) and Carpenter (US 6,150,423) both have effective dates under 35 U.S.C. § 102(e) later than the priority provisional application of the current invention (i.e., on April 5, 1999 and on October 15, 1998, respectively), neither document is competent as prior art for rejections under 35 U.S.C. § 103(a). The rejection on page 3 of the Action should be withdrawn as neither reference is available as prior art.

(III) **The Request for Abstract.** Attached is an abstract on a separate sheet required after publication of the application by the USPTO, please include in the response based on the text of the published PCT abstract.

(IV) **Lack of Clarity Rejections under 35 U.S.C. § 112.** Claims 1-12, 15-43, now new claims 45-76, are active in the current application. The Examiner has raised issues relating to lack of clarity in the claims of the current application: all claims are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner cites a number of items related to apparent lack of clarity in the claims. In order to address each item raised by the Examiner and to more particularly point out and distinctly claim that which the inventors consider to be their invention, amendments are

made below to claims 1, 2, 3, 10, 15, 19, 20, 21, 28, 29, 32, 36, and 41 consistent with the Examiner's comments and instructions to provide clarity, and claims 8, 22, 23, 26, 31, 33, 34, 37, and 43 have been deleted. Deleted claim 37 has been combined with claim 36 to form amended claim 36. Of the amended claims, claims 2, 3, 19, 20, 21, 28, 29, 32, and 36 have been amended to accommodate the Examiner's recommended Markush Group format.

Previous claims 1, 2, 3, 10, 15, 19, 20, 21, 28, 29, 32, 36, and 41 are rewritten as new claims 45-76 while claims 8, 22, 23, 26, 31, 33, 34, 37, and 43 are deleted to reduce issues.

In more detail, the amendments made to the previous claims are as follows, the new claim number indicated parenthetically:

**In claim 1 (45):**

The indefinite "**of**" (d) has been deleted and replaced with "and" that has been moved from the end of (d) for that purpose.

The term "**little**" in the word group "**little** or" has been deleted in the second bullet point of claim 1 (45).

The indefinite phrase "or other **suitable** length of time" has been deleted from the first point of claim 1 (45).

For additional clarification, the uncertainty between the choice of "**2 or 3**" has been resolved by the deletion of "or 3" in the second point of claim 1 (45).

The spelling of "**amphiphilic**" has been corrected in (e) of claim 1 (45), and the spelling of "**hours**" has been corrected in the second point. In addition, the redundant abbreviation "**(cfu)**" in the first point of claim 1 (45) has been deleted.

Also in claim 1 (45), the use of the terms "dispersion" (see claim 1, line 2) "composition" (see claim 1(e)) and "formulation" (see claim 45 following "wherein") have been used interchangeably prior to the current amendment. Each of "dispersion," "composition," and "formulation" refer without ambiguity and interchangeably to the composition that is claimed in claim 1 (45). Therefore, for consistency throughout claim 1 (45) and to provide a consistent antecedent for both the current and the modified

dependent claims 2 to 7 (46-51) and 9 to 12 (52-55), each of which already refer to "The composition" as an antecedent, the single unifying term "**composition**" has been selected and used throughout claim 1 (45). In this regard, the word "composition" has been copied from claim 1(45)(e) into line 1 of claim 1 (45), and "formulation" in claim 1 (45) has been replaced by the equivalent term "composition" just prior to the first bullet point and again twice inside the first bullet point.

**Claim 2 (46)** has been amended to incorporate the Examiner's request to list the terms in Markush format specified by the Examiner. Thus, the phrase "**the group consisting of**" has been added after "**selected from**," the last member is made "**and mixtures thereof**," the preceding members are **separated by commas**, and "**or**" has been deleted. This necessarily required the copying of the terms "ionizable phospholipid" and "non-ionizable phospholipid" and "cholesterol" that were previously combined in claim 2 (46) and pasting those words into individual terms (i.e., members of the group) in the selected sequence of four terms and mixtures thereof in amended claim 2 (46). The classification of surface modifiers into natural and synthetic surface modifiers has been eliminated by deletion. The term "**one or more**" has been deleted. The second part of claim 2 (46) that contained the vague terms "**minimum**" and "**minimized**" has been deleted.

**Claim 3 (47)** has been amended to incorporate the Examiner's directive to list the terms in the Markush format specified by the Examiner. Thus, the phrase "**selected from the group consisting of**" has been added after "is," the last member is made "**and mixtures thereof**" instead of "or a mixture thereof," the preceding members are **separated by commas**, and "**or**" has been deleted. This necessarily required the copying and pasting of the term "fatty acid triglyceride" and moving the term "natural" into the second item of the group. The term "or other **suitable** ester" has been deleted.

**Claim 8** has been deleted

**Claim 10 (53)** has been amended for clarity by the deletion of the redundant term "composition contains a."

**Claim 15 (56)** has been amended to delete the terms "**substantially limiting or**" and "**little or**" that were noted by the Examiner to be unclear. On page 16, under the heading "Inhibition of Microorganisms," the inventors outline how "the formulations described in the present invention were tested for their ability to inhibit the growth of microorganisms that are the potential source of most likely infections in the clinical situation." Subsequently, in the second paragraph of "Example 3, Inhibition of Microorganisms," the inventors explain that the "Inhibition of microbial growth was determined by a reduction or maintenance in the number of colonies of the inoculated microorganisms." Thus, the term "**inhibiting**" in claim 15 (56) specifically means "a reduction or maintenance in the number of colonies of the inoculated microorganisms," i.e., zero growth of microorganisms, and is not vague.

**Claim 19 (60)** has been amended to incorporate the Examiner's directive to list these terms in the Markush format specified by the Examiner. Thus, the phrase "**selected from the group consisting of**" has been added after "is," the last member is made "**and mixtures thereof**" instead of "or a mixture thereof," the preceding members are **separated by commas**, and "**or**" has been deleted. This necessarily required adjusting the terms "a pharmaceutically acceptable" and "fatty acid triglyceride" and moving the qualifying word "unsaturated" into the second term of the Markush group. The distinction between synthetic and natural has been eliminated, and both saturated fatty acids and unsaturated fatty acids as free acids rather than as triglycerides have been eliminated from the Markush group.

**Claim 20 (61)** has been amended to incorporate the Examiner's directive to list the terms in the Markush format specified by the Examiner. Thus, the phrase "**the group consisting of**" has been added after "**selected from**," the last member is made "**and mixtures thereof**," the preceding members are **separated by commas**, and "**or**" has been deleted. This necessarily required the copying and pasting of the terms "pharmaceutically acceptable esters of" and "fatty acids" and moving the terms "long chain" and "triglycerides" into the respective terms in the Markush group description.

Again, the distinction between materials of synthetic origin and natural origin has been deleted. The term "**one or more**" has been deleted.

**Claim 21 (62)** has been amended to incorporate the Examiner's directive to list such terms in the Markush format specified by the Examiner. Thus, the phrase "**the group consisting of**" has been added after "**selected from,**" the last member is made "**and mixtures thereof,**" the preceding members are **separated by commas**, and "**or**" has been deleted by deleting the term "**one or more.**" The trademarked term "Miglyol-810" has been deleted from the claim language.

**Claims 22, 23 and 26** have been deleted.

**Claim 28 (66)** has been amended to incorporate the Examiner's directive to list the terms in the Markush format specified by the Examiner. Thus, the phrase "**the group consisting of**" has been added after "**selected from,**" the last member is made "**and mixtures thereof,**" the preceding members are **separated by commas**, and "**or**" has been deleted. This necessarily required the copying and pasting of the terms "ionizable phospholipid" and "ionizable phospholipid" and "cholesterol" into the respective terms in the Markush group description. Again, the distinction between materials of synthetic origin and natural origin has been deleted. The term "**one or more**" has been deleted, and the term "**these amphiphilic agents**" has been deleted.

**Claim 29 (67)** has been amended to incorporate the Examiner's directive to list the terms in the Markush format specified by the Examiner. Thus, the phrase "**selected from the group consisting of**" has been added after "**is,**" the last member is made "**and mixtures thereof**" replacing the term "or a combination of these surface modifiers," the preceding members of the group are **separated by commas**, and each "**or**" has been deleted. This necessarily required the copying and pasting of the term "phospholipid of natural sources" from the second term into the first term of the group. The phrase "**one or more**" has been deleted.

**Claim 31** has been deleted.

**Claim 32 (69)** has been amended to incorporate the Examiner's directive to list the terms in the Markush format specified by the Examiner. Thus, the phrase "**selected from**

**the group consisting of**" has been added after **"is,"** the last member is separated by **"and,"** the preceding members of the group are **separated by commas**, and each **"or"** has been deleted.

**Claims 33 and 34** have been deleted.

**Claim 36 and claim 37** have been combined into new claim 71. Claim 36 (71) listed individual tonicity modifiers while claim 37 (71) listed a mixture of these same tonicity modifiers. Claim 36 (71) has therefore been amended to incorporate the Examiner's directive to list the terms in the Markush format specified by the Examiner. Thus, the phrase **"selected from the group consisting of"** has been added after **"is,"** the last member is made **"and mixtures thereof"** (from former claim 37), the preceding members are **separated by commas**, and **"or"** has been deleted.

**Claim 37** has been deleted.

**Claim 41 (75)** has been amended to be dependent on claim 40 (74) rather than to be dependent on claim 15 (56).

**Claim 43** which claimed a sealed vial containing the composition has been deleted.

In all dependent claims containing the word "wherein," a comma has been inserted before "wherein," i.e., after the claim number of the independent claim to which reference is made. These claims have not been noted to be amended.

No new matter has been added to the amended claims.

The amended/new claims are clearly stated, the examiner's concerns addressed and resolved, thus the rejection should be withdrawn.




The applied patent documents are not available as prior art, so the claims are in condition for allowance.

Reconsideration and favorable action are solicited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



Arthur R. Crawford  
Reg. No. 25,327

ARC:lsp  
1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100

